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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,529	01/07/2005	Annalisa Delnevo	07552.0051	9248

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,529	DELNEVO ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/05, 2/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

2. Claims 10, 50 are objected to because of the following informalities:

Claim 10 recites the limitation "said containing body" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "said second connecting element" in line 4. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6, 7, 28, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,578,223 to Bene et al.

In the specification and figures, Bene discloses the device as claimed by applicant. With regard to claim 1, Bene discloses an infusion system comprising a

container 10 with an infusion solution, a scale 23 to measure the weight of the container, an infusion line or transport line 11 that conveys the liquid from the container towards the patient, a pump 12 that conveys fluid along the line, a control unit 25 associated with the scale 23, and a bubble trap or separator 8 with an inlet that receives fluid from containers 10, 20 and an outlet that passes fluid to the rest of the infusion line (see column 3, lines 45-50, column 4, lines 3-29, FIG 1).

With regard to claims 6 and 7, Bene illustrates that the separator or bubble trap is placed between pump 12 and the infusion point on patient's arm 9, immediately downstream of the pump (see FIG 1).

With regard to claim 28, Bene illustrates that the infusion device may comprise several containers that connect to the infusion line via bubble trap 8, wherein each container has a valve or stop element (see FIG 1).

With regard to claims 49 and 50, Bene discloses and illustrates that the infusion set comprises an extracorporeal blood treatment circuit 5, 6, 7 and a blood treatment device in the form of dialyzer 1 (see FIG 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 25-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,223 to Bene et al.

In the specification and figures, Bene discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of the specific actions of the control unit. Bene discloses that the control unit 25 interacts with scales 23 and 24 of infusion fluids 10, 20, in order to control the movement of the fluid pumps 6, 12, 19, 22, thereby controlling the operation of the blood treatment procedure (see at least column 4, lines 7-67, column 5, lines 1-55). With this disclosure, Bene suggests that the controller may perform an end of infusion procedure when a certain condition, such as a weight change in the infusion containers, is detected by the scales, since Bene's controller continuously adjusts the pumping rates (which may include an adjustment to a zero flow rate) based on signals from the scales (see column 5, lines 22-45). As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to program the controller disclosed by Bene to perform an end of infusion procedure, such as stopping the infusion pumps, when a certain condition is detected by the controller, since Bene discloses that the controller is designed to continuously monitor and control fluid flow through the circuit.

7. Claims 2-5, 12-21, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,223 to Bene et al in view of US 4,190,426 to Ruschke.

In the specification and figures, Bene discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of a separator comprising various membranes within the separator or drip chamber. With regard to claims 2-5, 12,

and 13, Ruschke discloses a blood-gas separator that vents gas in a liquid stream. The separator comprises housing 10 (made up of base 12 and cover 14, defining fluid passages 37, 39), fluid inlet 20, fluid outlet 22, and vent ports or gas outlets 38 (see FIGS 1, 3, column 4, lines 13-29, column 4, lines 58-65). The separator further comprises a filter or selector means comprising a hydrophilic filter 24 with one side facing liquid inlet 20 and one side facing liquid outlet 22 (see FIG 1, column 4, lines 40-57). The separator still further comprises a selector or hydrophobic membrane 40 with one side facing the liquid inlet and channel 39 and one side facing the gas vent 38 (see column 6, lines 4-19, FIG 1). The filters are arranged within a fluid passage with the hydrophobic membrane located at the upper section of the hydrophilic membrane.

The filters disclosed by Ruschke allow for thorough and sterile venting of air from an infusion solution (see column 1, lines 10-20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the filter structure disclosed by Ruschke to the infusion set disclosed by Bene in order to provide through and sterile venting of air from an infusion set, as taught by Ruschke.

With regard to claims 14 and 15, base 12 comprises tubular connecting elements 20, 22. With regard to applicant's recitation that the base comprises one connector and the cover comprises the second connector, it is the position of the examiner that absent a showing of criticality of the position of the connectors on the base or cover, such an arrangement comprises an obvious rearrangement of the parts of the prior art. It has been held that rearranging parts of an invention found in the prior art involves only routine skill in the art. See MPEP 2144.04. In the instant case, it appears that the

position of the tube connectors on the base or cover do not affect the operation of the device, which would operate in the same manner whether the connectors were located on the base alone, base and cover, or cover alone.

With regard to claims 16 and 17, Ruschke illustrates that the hydrophilic membrane 24 is located between base 12 and cover 14 and extends the length of the body, parallel to and spaced from the base wall 16 (see FIG 1).

With regard to claims 18 and 20, Ruschke discloses that the base wall 16 comprises projections or ribs 28 (see column 5, lines 24-37, FIGS 1, 2).

With regard to claims 19 and 21, Ruschke discloses that base portion 12 comprises ribs that direct fluid to the outlet portion of the device (see column 5, lines 24-37), but fails to disclose that the cover portion comprises similar projections. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. See MPEP 2144.04. In the instant case, it is the position of the examiner that the ribs claimed by applicant on the cover portion are a duplication of the essential working parts of the device disclosed by Ruschke, since they operate in the same manner as the ribs disclosed in the prior art.

8. Claims 8-11, 22-24, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,223 to Bene et al in view of US 5,447,417 to Kuhl et al.

In the specification and figures, Bene discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of a rigid support or manifold that supports the tubing near the pump. With regard to claims 8 and 9, Kuhl discloses a fluid pumping apparatus with a molded manifold or support 400 that

supports a length of tubing 415 that is curved in such a manner to interact with a pump (see column 14, lines 51-67, FIG 4). The manifold is designed to allow for one-handed installation while preventing improper alignment (see column 14, lines 60-67). The manifold disclosed by Kuhl comprises an output port 411 to which a second length of tubing is attached to complete the circuit (see figures).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a support manifold as disclosed by Kuhl to the infusion system disclosed by Bene in order to allow for one-handed, properly aligned installation, as taught by Kuhl.

With regard to claims 10, 11, 22-24, and 41-42 as best understood by the examiner, Kuhl discloses that the manifold 400 comprises two lateral portions (generally at 415, 416) where the tubes manifold. The lateral portions are joined by rigid, straight cross-piece 412. For the purposes of examination, the examiner is assuming the "containing body" of claim 10 to refer to the separator recited in prior claims. Absent an argument from the applicant as to the criticality of the location and orientation of the separator within the rigid support, it is the position of the examiner that it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the separator and the manifold in a single piece, since it has been held that forming in one piece an article that has formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. In the instant case, the prior art clearly teaches the presence of all the claimed elements in a fluid transfer or infusion system. It is the position of the examiner that combining the previously

disclosed components into a single, integrated system is an obvious variation of the prior art.

9. Claims 30-32 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,223 to Bene et al in view of US 5,308,333 to Skakoon.

In the specification and figures, Bene discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of a check valve disposed on the infusion line downstream of the separator. Skakoon discloses an infusion set that delivers fluid from a pharmaceutical product bag to a patient (See column 3, lines 23-40). The set includes an air filter chamber 32 with an exit port that incorporates a one-way valve 46 in order to prevent reverse flow through the tube set (see column 3, lines 50-60). Therefore, it would have been obvious to add a check valve at the outlet of the air separator as disclosed by Skakoon to the infusion set disclosed by Bene in order to prevent reverse flow through the tube set, as taught by Skakoon.

10. Claims 34-37 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,223 to Bene et al in view of US 4,190,426 to Ruschke, further in view of US 5,308,333 to Skakoon.

The prior art discloses the apparatus substantially as claimed by applicant (see rejections above) with the exception of the position of the check valve within the housing of the separator. Absent any argument by applicant of the criticality of the location of the valve within the separator housing, it is the position of the examiner that it would have been obvious to one having ordinary skill in the art at the time the invention was made to place a check valve as disclosed by Skakoon within the housing of the separator

disclosed by Ruschke in the tube set disclosed by Bene, since it has been held that rearranging parts of an invention found in the prior art involves only routine skill in the art. See MPEP 2144.04.

11. Claims 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,223 to Bene et al in view of US 5,447,417 to Kuhl et al, further in view of in view of US 5,308,333 to Skakoon.

In the specification and figures, Bene and Kuhl disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a check valve formed integrally with a tubing manifold. Skakoon discloses a fluid infusion system with a check valve that prevents backflow through the infusion system. Absent an argument from the applicant as to the criticality of the location of the check valve integrated within the rigid support, it is the position of the examiner that it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the check valve and the manifold in a single piece, since it has been held that forming in one piece an article that has formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. In the instant case, the prior art clearly teaches the presence of all the claimed elements in a fluid transfer or infusion system. It is the position of the examiner that combining the previously disclosed components into a single, integrated system is an obvious variation of the prior art.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/520,667. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicant is claiming various combinations of the same elements of an infusion system in both applications. Applicant presents claims drawn to an identical separator, tube support, and check valve in each application, with each application presenting various combinations of the claimed elements. As such, the applications are unpatentable over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,769,811 Stacey et al

i. Blood processing system with tube manifold

b. US 5,605,540 Utterberg

ii. Infusion tube system with bubble trap

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
16 February 2007